

Claims

1. A process for the manufacture of a pharmaceutical preparation for the application of antiseptic agents and/or agents which promote the healing of wounds to the lower respiratory tract, characterised in that the preparation contains at least one of said agents combined with a particulate carrier.

2. The process of claim 1, characterised in that said particulate carrier comprises at least one of a liposome preparation, a microsphere preparation, a nanoparticle preparation, a Large Porous Particle preparation or a laser-pulse polymer coated molecule preparation.

3. The process according to claim 1 or 2, characterised in that at least the greatest part of said agent is encapsulated inside the carrier, especially a liposome or microsphere carrier.

4. The process of any one of claims 1 to 3, characterised in that the antiseptic agent is selected from oxygen- and halogen-releasing compounds; metal compounds, such as silver and mercury compounds; organic disinfectants including inter alia formaldehyde-releasing compounds, alcohols, phenols including alkyl- and arylphenols as well as halogenated phenols, quinolines and acridines,

hexahydropyrimidines, quaternary ammonium compounds and iminium salts, and guanidines.

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5. The process according to claim 4,  
5 characterised in that the antiseptic agent is selected from the group comprising metal compounds such as mercury compounds, phenol derivatives such as thymol, eugenol and hexachlorophene, iodine and iodine complexes.

6. The process according to claim 5,  
10 characterised in that the antiseptic agent is povidone iodine.

7. The process according to any one of claims 1 to 6,  
characterised in that the wound-healing promoting agent is selected from agents promoting granulation and epithelization such as dexpanthenol, allantoin, azulen, tannins, compounds from the vitamin B series, or similarly acting  
15 agents.

8. The process according to any one of the preceding claims,  
characterised in that the preparation contains at least one antiseptic and at least  
20 one wound-healing promoting agent.

9. The process according to any one of the preceding claims, characterised in that the carrier particles, especially liposomes, have a substantially uniform size in the range between about 1 and about 50  $\mu\text{m}$ , preferably in the range between about 1 and about 30  $\mu\text{m}$ .

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10. The process according to claim 9, characterised in that the carrier particles, especially liposomes, have a substantially uniform size in the range between about 20 and 30  $\mu\text{m}$  diameter for application to the trachea, in the range between about 10 and 20  $\mu\text{m}$  diameter for application to the bronchi and between about 1 and 6  $\mu\text{m}$ , especially between 2 and 5  $\mu\text{m}$ , diameter for application to the alveoli.

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11. The process according to any one of the preceding claims, characterised in that the carrier, especially liposome, preparation releases the agent over an extended time period, preferably an extended time period of several hours duration.

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12. The process according to claim 11, characterised in that the carrier, especially liposome, preparation releases the agent at approximately the same release rate over the release time period.

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13. The process according to any one of the preceding claims, characterised in that the preparation additionally comprises at least one anaesthetically active agent.

14. The process according to any one of the preceding claims, characterised in that the preparation contains additives and adjuvants such as conserving agents, antioxidants and consistency-forming additives.

15. The process according to any one of claims 1 to 14, the preparation being in a suitable form for administration via the lower respiratory tract comprising the active-agent loaded carrier, especially in the form of liposomes, preferably in the form of an aerosol, especially in the form of a powder aerosol.

16. The process according to any one of claims 1 to 14, the preparation being in the form of a compacted solid medicament reservoir, preferably a ring-tablet, more preferably a gelatin capsule, a powder, a spray, an emulsion, a dispersion, a suspension or a solution containing the carrier and agent or agents in a pharmaceutically acceptable solid or liquid formulation, which is suitable for the generation of inhalable particles.

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17. The process according to any one of the preceding claims, the preparation being in a suitable form for administration via the lower respiratory tract, which comprises:

- 5 a) liposomes comprising a pharmaceutically acceptable liposome membrane forming substance; and
- b) a 0.1 to 2 % PVP iodine solution (at approximately 10 % available iodine in the PVP iodine complex) at least most of which is encapsulated by said liposome membranes,

10 wherein the liposomes are of substantially uniform size between about 1 and about 50  $\mu\text{m}$ , and, in case, the formulation additionally comprises customary additives, adjuvants and auxiliary substances of a pharmaceutical formulation.

18. The process according to claim 17,

15 characterised in that the liposomes are of substantially uniform size, in the range between about 20 and 30  $\mu\text{m}$  diameter for application to the trachea, in the range between about 10 and 20  $\mu\text{m}$  diameter for application to the bronchi and between about 1 and 6  $\mu\text{m}$  diameter, preferably between about 2 and 5  $\mu\text{m}$  diameter, for application to the alveoli.

20 19. The process according to any one of claims 1 to 18, wherein the preparation is suited for the treatment of infectious diseases or alleviation of diseases such as HIV infections which are accompanied by opportunistic infections

or a suppressed immune system.

Al 5 20. The process according to any one of claims 1 to 18, wherein the preparation is suited for the treatment of acute and chronic bronchitis, pneumonia, bronchiectasia, cystic fibrosis, diphtheria and/or tuberculosis.

10 21. The process according to any one of claims 1 to 20, wherein the preparation is suited for functional and cosmetic tissue remodelling and repair treatments.

15 22. A method of preventing or treating infections of the human or animal lower respiratory tract, by applying, to said tract, a pharmaceutical preparation comprising at least one antiseptic agent and/or wound-healing promoting agent, said agent being combined with a particulate carrier in said preparation.

20 23. A method of functional and cosmetic tissue remodelling and repair in the human or animal lower respiratory tract, by applying, to said tract, a pharmaceutical preparation comprising at least one anti-inflammatory especially antiseptic and/or wound-healing promoting agent combined with a particular carrier.

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24. The method of claim 22 or 23, wherein said carrier comprises at least one of a liposome preparation, a microsphere preparation, a nanoparticle preparation, a Large Porous Particle preparation, or a laser-pulse polymer coated molecule preparation.

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25. The method of claim 22 or 23, wherein at least the greatest part of said agent is encapsulated inside the carrier, especially a liposome or microsphere carrier.

26. The method of claim 23, wherein the anti-inflammatory agent is selected from antiseptic agents, antibiotics, corticosteroids and wound-healing promoting agents.

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27. The method of claim 22 or 23, wherein the antiseptic agent is selected from oxygen- and halogen-releasing compounds; metal compounds, such as silver and mercury compounds; organic disinfectants including inter alia formaldehyde-releasing compounds, alcohols, phenols including alkyl- and arylphenols as well as halogenated phenols, quinolines and acridines, hexahydropyrimidines, quaternary ammonium compounds and iminium salts, and

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guanidines.

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28. The method of claim 22 or 23, wherein the antiseptic agent is selected from the group comprising metal compounds such as mercury compounds phenol derivatives such as thymol, eugenol and hexachlorophene, iodine and iodine complexes.

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29. The method of claim 22 or 23, wherein the antiseptic agent is povidone iodine.

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30. The method of claim 22 or 23, wherein the wound-healing promoting agent is selected from agents promoting granulation and epithelization such as dexpanthenol, allantoines, azulenes, tannines, compounds from the vitamin B series or similarly acting agents.

15 31. The method of claim 22 or 23, wherein the preparation contains at least one antiseptic and at least one wound-healing promoting agent.

32. The method of claim 22 or 23, wherein the carrier particles, especially liposomes, have a substantially uniform size in the range between about 1 and about 50  $\mu\text{m}$ , preferably in the range between about 1 and about 30  $\mu\text{m}$ .



33. The method of claim 32, wherein the carrier particles, especially liposomes, have substantially uniform size in the range between about 20 and 30  $\mu\text{m}$  diameter for application to the trachea, in the range between about 10 and 20  $\mu\text{m}$  diameter for application to the bronchi and between about 1 and 6  $\mu\text{m}$  diameter, especially between 2 and 5  $\mu\text{m}$ , for application to the alveoli.

34. The method of claim 22 or 23, wherein the carrier, especially liposome, preparation releases the agent over an extended time period, preferably an extended time period of several hours duration.

35. ~~The method of claim 22 or 23, wherein the carrier, especially liposome, preparation releases the agent at approximately the same release rate over the release time period.~~

36. The method of claim 22 or 23, wherein the preparation additionally comprises at least one anaesthetically active agent.

37. The method of claim 22 or 23, wherein the preparation contains additives and adjuvants such as conserving agents, antioxidants and consistency-forming additives.

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38. The method of claim 22 or 23, the preparation being in a suitable form for administration via the lower respiratory tract comprising the active-agent loaded carrier, especially in the form of liposomes, preferably in the form of an aerosol, especially in the form of a powder aerosol.

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39. The method of claim 22 or 23, the preparation being in the form of a compacted solid medicament reservoir, preferably a ring-tablet, more preferably a gelatine capsule, a powder, a spray, an emulsion, a dispersion, a suspension or a solution containing the carrier and agent or agents in a pharmaceutically acceptable solid or liquid formulation, which is suitable for the generation of inhalable particles.

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40. The method of claim 22 or 23, the preparation being in a suitable form for administration via the lower respiratory tract, which comprises:

- a) liposomes comprising a pharmaceutically acceptable liposome membrane forming substance; and
- b) a 0.1 to 2 % PVP iodine solution (at approximately 10 % available iodine in the PVP iodine complex) at least most of which is encapsulated by said liposome membranes,

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wherein the liposomes are of substantially uniform size between about 1 and about 50  $\mu\text{m}$ , and, in case, the formulation additionally comprises customary additives, adjuvants and auxiliary substances of a pharmaceutical formulation.

41. The method of claim 22 or 23, wherein the liposomes are of substantially uniform size, between about 20 and 30  $\mu\text{m}$  diameter for application to the trachea, between about 10 and 20  $\mu\text{m}$  diameter for application to the bronchi and between about 1 and 6  $\mu\text{m}$ , preferably between about 2 and 5  $\mu\text{m}$  diameter, for application to the alveoli.

42. The method of claim 22 or 23, wherein the preparation is suited for the treatment of infectious diseases or alleviation of diseases such as HIV infections which are accompanied by opportunistic infections or a suppressed immune system.

43. The method of claim 22 or 23, wherein the preparation is suited for the treatment of acute and chronic bronchitis, pneumonia, bronchiectasia, cystic fibrosis, diphtheria and/or tuberculosis.

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